UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,380	03/12/2004	Viia Valge-Archer	08702.0137-00000	6499

5514 7590 05/31/2007

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,380	VALGE-ARCHER ET AL.	
	Examiner	Art Unit	
	Elly-Gerald Stoica	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,38 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/28/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application/Claims

1. The amendment, filed 03/28/2007 has been entered. As a result of the amendment, claim 23 has been cancelled and currently claims 1-13, 15, 38, and the new claim 39 are pending.

Claim objections

2. Claim 39 is objected to for containing non-elected subject matter; since response to the restriction/election did not contain any grounds for traversal, the Seq. Id. Mentioned in the claim 39 constitute non-elected subject matter. Cancellation of the claim or in the subject matter referred to as non-elected subject matter is required.

Maintained claim rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description requirement

Possession of the Invention

Claims 1-13, 15, 38, and the new claim 39, remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description for the reasons of record. The arguments of the Applicant were carefully considered but not found to be

persuasive. The amendment to the claims to recite that the antibodies must bind to a polypeptide with at least 85% identity to either human (SEQ ID NO: 43) or mouse (SEQ ID NO: 45) IL-21 R, or a fragment thereof, with the requirement that the IL-21R or fragment thereof is capable of binding the IL-21 ligand still is insufficient to describe the genus of IL-21 receptor. The remaining 15% of the molecule is still not described until its reduction to practice. For instance the existence of an IL-21R of another specie that might be part of the IL-21R genus has to be first discovered and thus its description and possession is not adequate until reduction to practice. While the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function, if the Applicant intends to claim antibodies that bind to specific epitopes and these epitopes are within the sequence disclosed (i.e. in the 85 percentile of the genus claimed) that would constitute adequate written description. However, because of the breadth of the claims, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). See also< Tronzo v. Biomet, 156

F.3d at 1159, 47 USPQ2d at 1833 (Fed. Cir. 1998), >wherein< the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application.

The alignment cited as alleged evidence for possession of the genus (Applicant's remarks, p. 14, lines 1-4) is extraneous to the invention and it does not represent evidence of genus possession. The alignment might constitute evidence of the fact that the Applicant is enabled for antibodies for the mouse and human sequence of IL-21R. However the enablement evidence is not equated to the written description requirement since it constitute an invitation to discover and no conception is achieved until reduction to practice.

The Applicant argued that the description of other physical/chemical and structural properties of IL-21Rs are known in the art. (p.14 of the remarks, lines 15-20 and p.16, line 20 to p. 17, line 3). However, the evidence provided underscored the adequate written description for mouse and human IL-21 R but not for a sequence of at least 85% identity to the before mentioned receptors. The relationship between structure and functionality was not presented so that a person of ordinary skill in the art could not envision a clear correspondence between the antigenic epitopes of IL 21 R and the undisclosed portion of 15% of the molecule that might be antigenic by itself. Disclosure of an antigen **fully** characterized by "its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. Noelle v. Lederman, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (holding

there is a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described) (MPEP § 2163, II. Methodology for determining adequacy of written description). The description is adequate for the murine and human sequence and not for any other sequences irrespective of the % identity claimed.

Written description of the antibody

5. The arguments of the Applicant regarding the written description of the antibody were carefully considered but not found to be persuasive in their entirety. The Examiner agrees with the Applicant that, in certain situations, and antibody may be described by **three** CDRs, as kindly pointed to by the Applicant. However, the description of an antibody by less than **three** CDRs is still considered inadequate for an antibody for the reasons of record and therefore the rejection is maintained.

Scope of enablement requirement

6. Claims 1-13, 15, 38, and the new claim 39, remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record. As presented supra, a polypeptide that has the Seq. Id. No: 43 or 45 constitutes adequate written description for the murine or human IL-21 Receptor but not a sequence having an 85% sequence identity to either of the said sequences. Also, in the written description there is no evidence of association between the 85% identity of the human and mouse sequences with the uses mentioned in Applicant's remarks (p.19,

line 1). Accordingly, since about 15% of the protein would not have been adequately described, a person of ordinary skill in the art would not have known how to make antibodies against an undisclosed protein or what to use such an antibody for. The evidence cited by the Applicant (WO/01/85792, example 1) to rebut Examiner's conclusion of undue experimentation needed to make and use of antibodies raised against sequences other than the mouse and human IL-21 R actually show that the IL-21 R that was made according to the example is mouse and human IL-21 R and not other species. The antibody as claimed would bind to **any** 85% sequence identity with either the mouse or human IL-21 R, and the antibodies that have the CDRs claimed would have very narrow specificities, dictated by the stringent binding requirements as a consequence of the exact epitope that generated the CDRs; it is expected for the CDRs to bind to the exact epitope sequence or at least 95% sequence identity to satisfy the specificity claimed. Therefore the specification is enabling only for antibodies that bind the murine or the human IL-21 receptor of Seq. Id. Nos.: 43 and 45 or a sequence at least 95% identity to the respective sequences and the rejection is maintained.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15, 38, and the new claim 39, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the reasons of record. The arguments of the Applicant were carefully considered but not found to be persuasive because the description of a genus of polypeptides with at least 85% identity to the polypeptide set

forth in SEQ ID NO: 43 or SEQ ID NO: 45, or a fragment thereof, wherein the polypeptides in the genus are capable of binding IL-21, is still considered inadequate. The Examiner agrees with the Applicants contention that "An applicant is not required to use the best or most well-known term to describe a particular element; rather the test for indefiniteness is whether or not those skilled in the art would understand the scope of a claim when the claim is read in light of the specification." (p. 22, lines 6-9) but this does not constitute the issue here. Amended claims 4 and 5 contain language which still does not properly describe the antibodies properly and they remain rejected under the second paragraph of 35 U.S.C. 112. This situation is also present in the amended dependent claims 8-12, 15, and 38. Specifically, since one would not know what is the 15% of the molecule that the antibody is raised against, there is no knowledge if the antibody met the limitation of the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-13, 15, 38, and the new claim 39, remain rejected under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hodge MR (WO200069880, 11/23/2000) for the reasons of record. The arguments of the Applicant were carefully considered but not found to be persuasive because, while the Examiner

agrees that the presence of the sequences claimed is not explicitly disclosed by Hodges et al., the antibodies of Hodges et al. are consistent with the antibodies of the current application. The Applicant submitted "the Examiner has a burden of proving that the antibodies present in Hodge necessarily contain the CDR sequences recited in the pending claims" (p. 23, lines 18-19). However, due to the breadth of the claims, the antibodies of Hodges are more likely than not able to compete with the antibodies claimed in the instant Application. The Applicant, in the respective claims, does not claim specific antibodies but antibodies that compete with an antibody comprising a disclosed V_H, V_L, or scF_v amino acid sequence or isolated antibodies that bind the same epitope on an IL-21 receptor a polypeptide with at least 85% identity to the polypeptide. The antibodies of Hodges are consistent with the description in claims 6 and 7 presented above and thus anticipated or made the antibodies of claims 6 and 7 obvious.

With regard to the newly presented claim 39, the antibody claimed is defined by its structural and functional requirements and not by the method of making and therefore the considerations for the antibodies of the invention (written description, enablement and anticipation/obviousness) apply to this claim as for the other claims of the application.).

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LORRAINE SPECTOR
PRIMARY EXAMINER